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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,270	01/24/2002	David H. Mack	018501-005210US	2643
27194	7590	10/20/2004	EXAMINER	
HOWREY SIMON ARNOLD & WHITE, LLP C/O M.P. DROSOS, DIRECTOR OF IP ADMINISTRATION 2941 FAIRVIEW PK BOX 7 FALLS CHURCH, VA 22042			UNGAR, SUSAN NMN	
			ART UNIT	PAPER NUMBER
			1642	
DATE MAILED: 10/20/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/058,270

Applicant(s)

MACK ET AL.

Examiner

Susan Ungar

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on Interview of September 9, 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

1. In view of the telephone interview with U. Konz on September 24, 2004, the restriction requirement mailed September 9, 2004 is hereby vacated.
2. Claims 1-24 are pending in the application and are currently under prosecution.
3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group A. Claims 1-8 are drawn to hundreds, thousands, perhaps tens of thousands of distinct inventions, each of which is a method of detecting a breast cancer-associated transcript in a patient comprising contacting a biological sample from the patient with a polynucleotide that selectively hybridizes to a single sequence, or a variant thereof of one of the hundreds, thousands, perhaps tens of thousands of distinct sequences as shown in Tables 1-25 of the specification, classified in Class 435, subclass 6. It is noted that this is **not** an election of species requirement but rather a requirement to elect a single distinct group for examination. Applicant must elect a single group comprising a method using a single polynucleotide for examination

Group B. Claims 9-12 are drawn to hundreds, thousands, perhaps tens of thousands of distinct inventions, each of which is a single polynucleotide as shown in Tables 1-25, expression vector comprising said nucleic acid, a host cell comprising said expression vector, classified in Class 536, subclass 23.1, Class 435, subclasses 252.3, 320.1. It is noted that this is **not** an election of species requirement but rather a requirement to elect a single distinct group for examination. Applicant must elect a single polynucleotide for examination.

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Group C. Claim 13 is drawn to hundreds, thousands, perhaps tens of thousands of distinct inventions, each of which is a single polypeptide encoded by one of the hundreds, thousands, perhaps tens of thousands of polynucleotides as shown in Tables 1-25, classified in Class 530, subclass 350+. It is noted that this is **not** an election of species requirement but rather a requirement to elect a single distinct group for examination. Applicant must elect a single polypeptide encoded by a single polynucleotide for examination

4. It is noted that the claims of the instant application have been determined to include linking claims. Claim 14 links Groups D-E. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), 15. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group D. Claims 14-16, 18-19 are drawn to hundreds, thousands, perhaps tens of thousands of distinct inventions, each of which is a single antibody conjugated to a fluorescent label, or non-cytotoxic radioisotope as

contemplated by the specification, which binds to a polypeptide encoded by one of the hundreds, thousands, perhaps tens of thousands of polynucleotide as shown in Tables 1-25, classified in Class 530, subclass 387.1. It is noted that this is **not** an election of species requirement but rather a requirement to elect a single distinct group for examination. Applicant must elect an antibody conjugated to a non-toxic label to a single polypeptide encoded by a single polynucleotide for examination.

Group E. Claims 14-15, 17-19 are drawn to hundreds, thousands, perhaps tens of thousands of distinct inventions, each of which is a single antibody conjugated to a cytotoxic chemical or cytotoxic radioisotope which binds to a polypeptide encoded by one of the hundreds, thousands, perhaps tens of thousands of polynucleotides as shown in Tables 1-25, classified in Class 530, subclass 387.1. It is noted that this is **not** an election of species requirement but rather a requirement to elect a single distinct group for examination. Applicant must elect an antibody, conjugated to a toxic label, to a single polypeptide encoded by a single polynucleotide for examination.

Group F. Claims 20-22 are drawn to hundreds, thousands, perhaps tens of thousands of distinct inventions, each of which is a method of detecting a breast cancer cell in a biological sample from a patient sample comprising contacting said sample with a labeled antibody to an antibody which binds to one of the hundreds, thousands, perhaps tens of thousands of polypeptides encoded by a polynucleotide as shown in Tables 1-25, classified in Class 530, subclass 387.1. It is noted that this is **not** an election of species requirement but rather a requirement to elect a single distinct group for examination.

Applicant must elect an method using a single antibody to a single polypeptide encoded by a single polynucleotide for examination.

Group G. Claim 23 is drawn to hundreds, thousands, perhaps tens of thousands of distinct inventions, each of which is a method of identifying a compound that modulates a breast cancer associated polypeptide comprising contacting a breast cancer-associated polypeptide encoded by a polynucleotide that selectively hybridizes to one of the hundreds, thousands, perhaps tens of thousands of sequences as shown in Tables 1-25, classified in Class 435, subclass 4. It is noted that this is **not** an election of species requirement but rather a requirement to elect a single distinct group for examination. Applicant must elect a method using a single polypeptide encoded by a single polynucleotide for examination.

5. It is noted that the claims of the instant application have been determined to include linking claims. Claim 24 links Groups H-I. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), 15. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of

35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group H. Claim 24 is drawn to hundreds, thousands, perhaps tens of thousands of distinct inventions, each of which is a drug screening assay comprising administering a test compound and comparing mRNA gene expression, as contemplated by the specification, of a polynucleotide that selectively hybridizes to one of the hundreds, thousands, perhaps tens of thousands of sequences as shown in Tables 1-25 with control, classified in Class 435, subclass 6. It is noted that this is **not** an election of species requirement but rather a requirement to elect a single distinct group for examination. Applicant is required to elect a single invention, a method of assaying for a single polynucleotide for examination.

Group I. Claim 24 is drawn to hundreds, thousands, perhaps tens of thousands of distinct inventions, each of which is a drug screening assay comprising administering a test compound and comparing gene product at the level of protein, as contemplated by the specification, of a polynucleotide that selectively hybridizes to one of the hundreds, thousands, perhaps tens of thousands of sequences as shown in Tables 1-25 with control, classified in Class 435, subclass 7.1. It is noted that this is **not** an election of species requirement but rather a requirement to elect a single distinct group for examination. Applicant is required to elect a single method using the level of a single protein encoded by a polynucleotide that hybridizes to a single polynucleotide for examination.

6. The inventions are distinct, each from the other because of the following reasons:

Groups B/C/D/E as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Inventions A/F-I are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups B and A/H are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the nucleic acid products as claimed can be used in a materially different process such as in the production of polypeptide.

The inventions of Groups B and A/H are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the nucleic acid products as claimed can be used in a materially different process such as in the production of polypeptide.

The inventions of Groups D/C and F/G/I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed

can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case both of the polypeptide and antibody products as claimed can be used in a materially different process such as in the production of antibody and anti-idiotypic antibody, respectively.

The inventions of Groups B and F/G/I are not at all related because the nucleic acid of Group B is not used in any of the methods of Groups F/G/I.

The inventions of Groups C/D and A/I not at all related because neither the polypeptide of Group C nor the antibody of Group D not used in any of the methods of Groups A/I.

The inventions of Groups E and A/F/G/H/I not at all related because the cytotoxic antibody of Group E is not used in any of the methods of Groups A/F/G/H/I.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Group A is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the methods comprise assaying a patient who is undergoing a therapeutic regiment to treat breast cancer (claim 7), assaying a patient who is suspected of having breast cancer (claim 8).

9. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

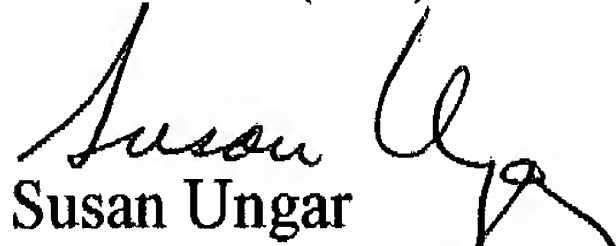
11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 308-0787. The fax phone number for this Art Unit is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Susan Ungar

Primary Patent Examiner

October 11, 2004